

from compliance with some structural standards.

*Comment:* One commenter stated that the protocols being developed are, in fact, EQR-related activity protocols and that there does not appear to be any protocol that will guide the analysis and evaluation of the data and information provided by these EQR-related activities. This may cause the analysis and evaluation to vary due to lack of equivalent specifications for these processes. The commenter recommended that the rule more clearly define requirements for EQR and distinguish between EQR and EQR-related activities.

*Response:* The commenter is correct that we do not provide a protocol for the analysis and evaluation of information provided as a result of the EQR activities in the aggregate. We do not believe that we should develop a protocol for the analysis and evaluation of all EQR information. The information derived from EQR activities will vary enormously. For instance, the variation in the types of services provided and the populations covered under the MCO and PIHP contract will impact the performance measures chosen and performance improvement projects to be conducted. Other activities are optional for States. The approach to analysis depends upon the findings of the individual EQR-related activities and we expect these findings to be as individual as the MCOs and PIHPs being reviewed. Therefore, we do not believe that we can adequately predict all the possible variations of information that will be provided to an EQRO and, therefore, we do not provide for a protocol on how to conduct an analysis and evaluation of this information. We believe it is more appropriate for us to require that the activities that provide information for the analysis and evaluation be done in a methodologically sound manner. We do specify qualifications for EQROs and thereby believe that EQROs will have the skills necessary to perform qualitative and quantitative analysis of EQR-related information and draw proper conclusions. In addition, each EQRO must provide results as specified in § 438.364 that include a technical report specifying the objectives of, methods used, description of data obtained, and conclusions drawn from the EQR.

*Comment:* Many commenters were concerned that there has been no public review process for the protocols and that the meetings of the expert panel have been closed to the public. The commenters recommended that the public have the opportunity to review

and comment on the draft protocols, that the protocols be issued annually, and the public have the opportunity to comment on any changes to the protocols. The commenters also stated that the protocols should be made publicly available on the CMS website. Several commenters asked that we provide an opportunity for interested parties and the public to comment on the protocols. They noted that providing the opportunity for all affected entities to review and provide comment on the protocols before they are finalized will allow for a better quality product and lend credibility to the protocols. One of the commenters further noted that even though CMS convened an expert panel to review the protocols as they were being developed, consumer participation was very limited.

*Response:* As stated earlier, on November 23, 2001, we published a notice in the **Federal Register** announcing the completion of the protocols and requesting comment on their burden or on any other aspect of the protocols. Comments on that notice and our responses to those comments are incorporated into this preamble. We will be publishing a notice in the **Federal Register** every 3 years on the protocols as required by the Paperwork Reduction Act. This notice will provide the opportunity for the public to comment on the burden or any other aspect of the protocols. The protocols are available to the public on the CMS Web site at <http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp>.

*Comment:* One commenter requested that in developing the protocols, JCAHO take into consideration that some factors that affect MCO performance are not within the control of the MCO, such as instability in eligibility status and changes in the characteristics of the enrolled Medicaid population.

*Response:* We agree that measuring performance on the Medicaid population needs to take into account issues such as changes in eligibility status. The protocol on performance measures recognizes those issues.

*Comment:* Because of the length of the protocols and the need to change them on an ongoing basis, one commenter requested that we clarify that the protocols be issued as guidelines rather than requirements and that we clarify the flexibility States will have in implementing them.

*Response:* Section 1932(c)(2)(A)(ii) of the BBA requires that protocols be used in the conduct of EQR activities. We provide States the option to use our protocols or protocols consistent with those we develop.

#### *E. Qualifications of External Quality Review Organizations (§ 438.354)*

Section 438.354 of the proposed rule set forth the requirements that an entity would be required to meet in order to qualify as an EQRO under the new BBA external review provisions in section 1932(c)(2) of the Act. The proposed rule did not specify categories of entities that would be qualified to perform EQR under section 1932(c)(2) of the Act. This is a departure from the existing external review requirement in section 1902(a)(30)(C) of the Act (which will no longer be in effect when these final regulations are implemented), under which only certain entities could perform external review. (These entities were: (1) A “quality improvement organization” (QIO) that contracts with Medicare to perform review (QIOs were formerly known as quality control peer review organizations, or “PROs”); (2) an entity that meets the requirements to contract with Medicare as a QIO; and (3) a private accreditation body. Only contracts with the first two categories were eligible for a 75 percent matching rate under the pre-BBA rules.)

Under proposed § 438.354, in order to qualify, entities would be required to meet specified competence and independence standards. We proposed two tests of independence. Under the first proposed test, the EQRO and any subcontractors would have to be independent from the State Medicaid agency and from any MCO or PHP they review. Second, the relationship between the MCO/PHP and the EQRO could not involve any potential conflicts of interest. We specifically requested comments on (1) how better to identify situations that create conflict of interest; (2) the proposal to allow State entities to qualify as EQROs; and (3) our decision in the proposed rule to apply the “independence” requirement to subcontractors as well as contractors.

We also proposed that EQROs be selected by State agencies through an open, competitive procurement process. As noted in the preamble to the proposed rule, CMS would not, under our proposal, approve EQR contracts. However, contracts entered into by the States would be subject to review to ensure that, as a condition for FFP at the 75 percent rate, the State agency followed all applicable procedures and criteria. This proposed procedure is consistent with current practice, which is for State agencies to use competitive procurements to select EQROs that perform review under section 1902(a)(30)(C) of the Act. It is also standard practice for our regional office staff to monitor implementation of